

REMARKS

By the present Amendment, claims 11, 14, 15, 17, 20-23 and 25 are amended, claim 16 is cancelled, and claim 29 is added. This leaves claims 11-15 and 17-29 pending in the application, with claims 11, 14, 23 and 29 being independent.

The withdrawal of the finality of the August 14, 2009 Office Action in the September 4, 2009 Office Action is noted with appreciation.

Rejections Under 35 U.S.C. §102 and §103

Claim 11 covers a method for endoscopic application of self-closing medical clips comprising the steps of placing a distal end of a catheter tube 1 in a body of a living being to be treated, arranging at least one self-closing clip 3 with relatively movable legs 5 in the catheter tube adjacent the distal end by an operator located on a proximal end of the catheter tube, pushing the clip out of the distal end, opening the clip by an actuator having an actuator element 17, 21 with a pull cable 21 acting on the clip, being movable longitudinally in the catheter tube and actuated by the operator and having a control part converting an actuating force of the actuating element into a motion opening the legs of the clip. The actuating element is detached from the clip after opening of the clip to release the clip and close the legs of the clip to apply the clip. The clip has a first kink 13 in a first area of each leg extending outwardly and increasing a distance between the legs and a second kink 15 in a second area nearer the distal end 7 of the clip than the first area, but spaced from that distal end, extending inwardly and forming a point of mutual support for the legs. A rear end crosspiece 9 connects the clip legs and has two adjacent through holes 11 through which the pull cable extends in a loop connecting an advancing strand

extending from the operator to the rear end crosspiece to a retreating strand extending to the operator from the rear end crosspiece.

Claim 14 combines the limitations of previous claims 14-16 except for the beveled control surface, and is directed to a device for endoscopic application of self-closing medical clips in a body of a living being comprising a catheter tube 1, an operator, an actuator and at least one clip 3. The catheter tube has a distal end placeable in a body and a proximal end placeable outside the body. The operator is at the proximal end. The actuator extends in the catheter tube from the operator to an area adjacent the distal end, has an actuating element 17, 21 with a pull cable 21 movable longitudinally in the catheter tube and controlled by the operator, and has at least one control part with a distal end edge 25 on a sleeve-shaped receiving part 33. The clip is adjacent to and directly engages the distal end edge and has a part received in the actuating element and two adjacent legs 5. The legs have first kinks 13 extending outwardly and increasing a distance between the legs in first areas of the legs and second kinks 15 extending inwardly and forming a mutual support for the legs in second areas of the legs nearer to a distal leg end of the clip than the first area, but spaced from that distal end without the legs crossing one another. The clip legs are coupled to the pull cable by a rear end crosspiece 9 connecting the clip legs and having two adjacent through holes 11 through which the pull cable extends in a loop connecting an advancing strand extending from the operator to the crosspiece to a retreating strand extending to the operator from the crosspiece. The legs are opened by the first kinks engaging the control part when the clip is inserted into the sleeve-like receiving part which converts an actuating force of the actuating element into an opening motion of the legs with the second areas engaging one another.

Claim 23 covers a self-closing medical clip 3 comprising a crosspiece 9, and first and second legs 5 extending adjacent to one another from the crosspiece to distal ends thereof and biased toward one another. First kinks 13 in the legs extend outwardly and increase a distance between the legs in first areas of the legs. Second kinks 15 in the legs extend inwardly and form a mutual support for the legs in second areas of the legs. The second areas are nearer the distal ends than the first areas. The clip legs are coupled to a pull cable 21 by the crosspiece 9 extending between and directly connecting the clip legs and having two adjacent through holes 11 through which the pull cable extends in a loop connecting an advancing strand extending to the crosspiece and a retreating strand extending away from the crosspiece and laterally adjacent the advancing strand.

By performing the method, forming the device and forming the clip in this manner, a simple and effective mechanism is provided in which the clips can be formed and then applied. The mutual support provided by the second kinks in the second areas allow the remaining portion of the legs to pivot outwardly when the first kink is compressed with the pivoting motion being initiated at the contact of the second kinks. The clip movement is controlled by the pull cable attached by the holes in the clip crosspiece. None of the clips of the cited patent documents are formed or operated in this manner.

Claims 11, 12, 14, 15, 23, 24 and 26-28 stand rejected under 35 U.S.C. §102 as being anticipated by the newly cited U.S. Patent Publication No. 2002/0177861 to Sugiyama. The Sugiyama publication is cited for disclosing a method and a device for self-closing medical clips where a clip has two movable legs 111 in a catheter tube 130, and where the clips have a first kink 114b and a second kink 114a allegedly, as claimed. An actuator formed by parts 131, 134,

120 and 135 allegedly has an actuating element 131, 134 acting on the clip and movable in the tube and actuatable by an operator having a control part 120 to open the clip legs with the legs allegedly being symmetrical in Fig. 15. The kinks 114a and 114b are alleged to be shaped, as claimed. The reference to “Kobayashi et al” in the middle of page 3 of the Office Action appears to be a mistake, and apparently should refer to “Sugiyama”.

Claims 13 and 25 stand rejected under 35 U.S.C. §103 as being unpatentable over the Sugiyama publication in view of the previously cited U.S. Patent Publication No. 2002/0128667 to Kobayashi. The Kobayashi publication is cited for the use of plural medical clips and the use of a predetermined breaking point between adjacent through holes. In support of the rejection, it is alleged that it would be obvious to use plural clips in the Sugiyama device and to provide the predetermined breaking point between adjacent through holes in the Sugiyama clip.

Claims 11, 14 and 23 are patentably distinguishable over the Sugiyama publication considered above or in any obvious combination with the Kobayashi publication by use of or the provision of a pull cable extending in a loop through holes in the clip crosspiece connecting the clip legs, particularly in combination with the other claimed method steps or claimed structure. This claimed connection of the pull cable with the clip crosspiece and the use thereof are not disclosed or rendered obvious by the cited and applied patent publications.

The Sugiyama publication discloses a number of different clip arrangements, with the first embodiment shown in Fig. 2 apparently being relied upon. Clip 110 is coupled to connecting string 115 with that string being passed between base end portion 113 of clip 110 and rear end surface 121c of core member 12 (para. 99). Further details of this connection do not appear to be provided. Sugiyama base end portion is not disclosed as having two through holes

with string 115 passing through those holes, as claimed. Further, the Sugiyama constriction 114a interpreted as second kinks are separated by small diameter portion 121a of core member 121 such that the Sugiyama clip 110 does not have second kinks that extend inwardly to form a mutual support point for the clip legs, as claimed.

The Sugiyama clip 110 shown in Figs. 32-39 has a pair of arms extending from an annular end portion 113. A boundary portion 117 is formed in a constricted shape. Operating wire 131 is connected to clip 110 by connecting member 137 and connecting hook 134 with connecting hook tip portion 134c engaged in connecting hole 113a of clip 110. Thus, the Sugiyama publication does not disclose or render obvious the claimed connection of the pull cable and the clip with the cable extending in a loop through two holes in the crosspiece connecting the clip legs, as claimed.

Accordingly, claims 11, 14 and 23 are patentably distinguishable over the Sugiyama publication. These deficiencies in the Sugiyama publication are not provided by the Kobayashi publication.

The Kobayashi publication would not render obvious the use of plural medical clips or a pull cable extending through adjacent holes in a clip crosspiece in the Sugiyama device, as alleged. The structure and arrangement of the Sugiyama and Kobayashi devices are so different that substantial modification would be required in the Sugiyama device to adapt it to the use of plural clips. The substantial modification necessary is not taught or rendered obvious to one of ordinary skill in the art since there is no teaching of how to incorporate the Kobayashi plural clip arrangement in the Sugiyama single clip device.

For the embodiment shown in Fig. 7c of the Kobayashi publication, a manipulating wire 9 is connected to the base of clip 3 by an annular ligating wire 10, which ligating wire 10 contains a notch. Such arrangement does not provide a crosspiece in the clip with two holes in that crosspiece through which the manipulating wire 9 passes. As such, the Kobayashi publication not teach the features of claims 11, 14 and 23 noted as being missing in the Sugiyama publication.

Accordingly, claims 11, 14 and 23 are patentably distinguishable over the Sugiyama and Kobayashi publications. None of the other cited patents supply these deficiencies.

Claims 12-13 and 27, claims 15, 17, 22 and 28 and claims 24-26, being dependent upon claims 11, 14 and 23, respectively, are also allowable for the above reasons. Moreover, these dependent claims recite additional features further distinguishing them over the cited patents.

Claim 12 is further distinguishable by the form of the legs, particularly within the claimed combination.

Claim 13 is further distinguishable by the additional other clips and the functional linking of the various clips. Such use of plural clips is not rendered obvious in view of the Kobayashi publication, as noted above.

Claim 15 is further distinguishable by the claimed internal beveled control surface on the distal end edge of the sleeve-shaped receiving part. No such beveled edge is disclosed or rendered obvious by the Sugiyama publication. The Sugiyama ring 120 does not have a beveled control surface, and particularly does not have an internal beveled control surface at its distal end edge.

Claim 17 is further distinguishable by the breaking point between the two parallel and laterally offset through holes. Neither the crosspiece of the clip 3 nor wire 10 of the Kobayashi publication has those two through holes or the breaking point between those through holes.

Claim 18 is further distinguishable by the blocking element recited therein, particularly within the overall claimed combination.

Claim 19 is further distinguishable by the blocking element being in the form of a collet with jaws.

Claim 20 is further distinguishable by the multiple clips within the overall claimed combination, for the reasons advanced above.

Claim 21 is further distinguishable by the actuator being a tube within the overall claimed combination.

Claim 22 is further distinguishable by the axial projection on the sleeve-shaped receiving part, particularly within the overall claimed combination.

Claim 24 is further distinguishable by the legs not crossing one other.

Claim 25 is further distinguishable by the crosspiece having two parallel and laterally offset holes adjacent one another with a predetermined breaking point therebetween which is not present in the Kobayashi clip, as discussed above.

Claims 26-28 are further distinguishable by the bent distal ends spaced from the second kinks.

Claim 29 covers a method for endoscopic application self-closing medical clips. The method comprises the steps of placing a distal end of a catheter in a body of a living being to be treated; arranging at least one self-closing medical clip with relatively movable legs in the

catheter tube adjacent the distal end by an operator located on a proximal end of the catheter tube, with the clip having a first kink in a first area of each leg extending outwardly and increasing a distance between the legs and a second kink in a second area nearer the distal leg end of the clip than the first area but spaced from the distal end extending inwardly and forming a point of mutual support for the legs; pushing the clip out of the distal end; opening the clip by an actuator having an actuating element acting on the clip, being movable longitudinally in the catheter tube, being actuated by an operator and having a control part converting an actuating force of the actuating element into a opening motion of the legs of the clip by pressing on each first kink inwardly to cause the legs to pivot at and about the mutual support such that the leg portions located between the second kinks and the distal leg ends open; and detaching the actuating element from the clip after opening of the clip to release and close the legs of the clip to apply the clip by the resiliency of the clip alone without attaching another member to the clip.

In contrast, the embodiments of the Sugiyama publication require the mounting of a clip open-close ring 120 to secure the clip in its closed position, as shown, for example, in Figs. 12-14. Similarly, the Kobayashi device requires a clip tightening 29, as illustrated, for example, in Figs. 17d and 22d of that publication. Claim 29 is further distinguishable over the cited publications by the specifically recited opening procedure in combination with the clip closing without the placement of another member on the clip.

In view of the foregoing, claims 11-15 and 17-29 are allowable. Prompt and favorable action is solicited.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Mark S. Bicks", is written over a horizontal line.

Mark S. Bicks
Reg. No. 28,770

Roylance, Abrams, Berdo & Goodman, LLP
1300 19th Street, NW, Suite 600
Washington, DC 20036
(202) 659-9076

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